CLAIMS

1. A polypeptide having β1,3-galactosyltransferase activity involved in the synthesis of sialyl-Lewis a sugar chain, present in colon cancer cells expressing sialyl-Lewis a sugar chain.

2. A polypeptide selected from the group consisting of:

(a) a polypeptide consisting of the amino acid sequence represented by SEQ ID NO: 1,

(b) a polypeptide containing the amino acid sequence of 31 to 310 in the amino acid sequence represented by SEQ ID NO: 1, and

(c) a polypeptide consisting of an amino acid sequence where in the amino acid sequence of the polypeptide (a) or (b), one or more amino acids have been deleted, replaced or added and having β1,3-galactosyltransferase activity capable of synthesizing Galβ1-3GlcNAc structure.

3. A polypeptide according to claim 1 or 2 wherein the β1,3-galactosyltransferase activity is the activity of transferring galactose via β1,3-linkage to N-acetylglucosamine residue present at the non-reducing terminus of a sugar chain.

4. A polypeptide according to claim 1 or 2 wherein the β1,3-galactosyltransferase activity is the activity of transferring galactose via β1,3-linkage to N-acetylglucosamine residue present at the non-reducing terminus of GlcNAcβ1-3Galβ1-4Glc or to N-acetylglucosamine monosaccharide.

5. A DNA selected from the group consisting of:

(a) DNA coding for the polypeptide described in any one of claims 1 to 4,

(b) DNA having the nucleotide sequence of 402 to 1331 in the nucleotide sequence represented by SEQ ID NO: 2,

(c) DNA having the nucleotide sequence of 492 to 1331 in the nucleotide sequence represented by SEQ ID NO: 2, and

(d) DNA hybridizing under stringent conditions with the DNA described in any of (a) to (c) and coding for a polypeptide

having β1,3-galactosyltransferase activity capable of synthesizing Galβ1-3GlcNAc structure.

6. A recombinant DNA prepared by integrating the DNA described in claim 5 into a vector.

7. A recombinant DNA according to claim 6 which is plasmid pAMo-3GT5 or plasmid pBS-3GT5 (FERM BP-6645).

8. A transformant harboring the DNA described in claim 5, the recombinant DNA in claim 6 or the recombinant DNA in claim 7.

9. A transformant according to claim 8 which is a member selected from the group consisting of a microorganism, an animal cell, a plant cell, an insect cell, a non-human transgenic animal and a transgenic plant.

10. A transformant according to claim 9 wherein the microorganism is a microorganism belonging to the genus *Escherichia*.

11. A transformant according to claim 9 wherein the animal cell is a member selected from the group consisting of a mouse myeloma cell, a rat myeloma cell, a mouse hybridoma cell, a CHO cell, a BHK cell, an African green monkey kidney cell, a Namalwa cell, a Namalwa KJM-1 cell, a human embryonic kidney cell and a human leukemia cell.

12. A transformant according to claim 9 wherein the insect cell is a member selected from the group consisting of a *Spodoptera frugiperda* ovarian cell, a *Trichoplusia ni* ovarian cell and a silkworm ovarian cell.

13. A process for producing the polypeptide described in any one of claims 1 to 4, which comprises culturing a transformant harboring a recombinant DNA prepared by integrating DNA coding for the polypeptide of any one of claims 1 to 4 into a vector in a medium to thereby form and accumulate said polypeptide in the culture, and collecting said polypeptide from said culture.

14. A process for producing the polypeptide described in any one of claims 1 to 4, which comprises breeding a non-human transgenic animal harboring a recombinant DNA prepared by

integrating DNA coding for the polypeptide of any one of claims 1 to 4 into a vector to thereby form and accumulate said polypeptide in said animal, and collecting said polypeptide from said animal.

15. A process according to claim 14 wherein formation and accumulation occur in animal milk.

16. A process for producing the polypeptide described in any one of claims 1 to 4, which comprises culturing a transgenic plant harboring a recombinant DNA prepared by integrating DNA coding for the polypeptide of any one of claims 1 to 4 into a vector to thereby form and accumulate said polypeptide in said plant, and collecting said polypeptide from said plant.

17. A process for producing the polypeptide described in any one of claims 1 to 4, which comprises synthesizing the polypeptide of any one of claims 1 to 4 in an <u>in vitro</u> transcription-translation system using DNA coding for said polypeptide.

18. A process for producing a reaction product having galactose, which comprises using the polypeptide of any one of claims 1 to 4 as an enzyme source, and allowing

(a) said enzyme source,

(b) an acceptor substrate selected from the group consisting of:

i) N-acetylglucosamine (GlcNAc),

ii) an oligosaccharide having N-acetylglucosamine residue at the non-reducing terminus thereof, and

iii) a complex carbohydrate having N-acetylglucosamine residue at the non-reducing terminus thereof, and

(c) uridine-5′-diphosphate galactose to be present in an aqueous medium to thereby form and accumulate said reaction product in the aqueous medium, and collecting said reaction product from said aqueous medium, wherein the galactose is transferred via β1,3-linkage to N-acetylglucosamine or N-acetylglucosamine residue of said acceptor substrate.

19. A process for producing a reaction product having

galactose, which comprises using the polypeptide of any of claims 1 to 4 as an enzyme source, and allowing

(a) said enzyme source,

(b) an acceptor substrate selected from the group consisting of:

i) glucose,

ii) an oligosaccharide having glucose residue at the non-reducing terminus thereof, and

iii) a complex carbohydrate having glucose residue at the non-reducing terminus thereof, and

(c) uridine-5'-diphosphate galactose to be present in an aqueous medium to thereby form and accumulate said reaction product in the aqueous medium, and collecting said reaction product from said aqueous medium, wherein the galactose is transferred via β1,3-linkage to glucose or glucose residue of said acceptor substrate.

20. A process for producing a sugar chain or a complex carbohydrate, which comprises culturing the transformant selected from the group consisting of transformants of claim 9 derived from a microorganism, an animal cell, a plant cell and an insect cell in a medium to thereby form and accumulate a sugar chain having galactose transferred via β1,3-linkage to N-acetylglucosamine, N-acetylglucosamine residue, glucose or glucose residue thereof or a complex carbohydrate containing said sugar chain in the culture, and collecting said sugar chain or said complex carbohydrate from said culture.

21. A process for producing a sugar chain or a complex carbohydrate, which comprises breeding the non-human transgenic animal of claim 9 to thereby form and accumulate in said animal a sugar chain having galactose transferred via β1,3-linkage to N-acetylglucosamine, N-acetylglucosamine residue, glucose or glucose residue thereof or a complex carbohydrate containing said sugar chain, and collecting said sugar chain or said complex carbohydrate from said animal.

22. A process for producing a sugar chain or a complex carbohydrate, which comprises culturing the transgenic plant

of claim 9 to thereby form and accumulate in said plant a sugar chain having galactose transferred via β1,3-linkage to N-acetylglucosamine, N-acetylglucosamine residue, glucose or glucose residue thereof or a complex carbohydrate containing said sugar chain, and collecting said sugar chain or said complex carbohydrate from said plant.

23. A process according to any one of claims 18 to 22 wherein the complex carbohydrate is a complex carbohydrate selected from the group consisting of a glycoprotein, a glycolipid, a proteoglycan, a glycopeptide, a lipopolysaccharide, a peptidoglycan and a glycoside which is a steroid compound with a sugar chain.

24. A process according to claim 21 wherein formation and accumulation occur in animal milk.

25. A method for determining the expression level of a gene encoding the polypeptide of any one of claims 1 to 4, which comprises hybridization using DNA coding for said polypeptide or a fragment of said DNA.

26. A DNA selected from the group consisting of an oligonucleotide having the same nucleotide sequence as a consecutive 5- to 60-nucleotide sequence in the nucleotide sequence of the DNA of claim 5 or of a DNA having the nucleotide sequence represented by SEQ ID NO: 2 or 3, an oligonucleotide having a sequence complementary to said oligonucleotide, and an oligonucleotide derivative of any of said oligonucleotides.

27. A DNA according to claim 26 wherein the oligonucleotide derivative is selected from the group consisting of an oligonucleotide derivative in which the phosphodiester bond is converted into a phosphorothioate bond, an oligonucleotide derivative in which the phosphodiester bond is converted into an N3'-P5'-phosphoamidate bond, an oligonucleotide derivative in which the ribose and the phosphodiester bond are converted into a peptide-nucleic acid bond, an oligonucleotide derivative in which the uracil is replaced by a C-5 propynyluracil, an oligonucleotide derivative in which the uracil is replaced by a C-5

thiazolyluracil, an oligonucleotide derivative in which the cytosine is replaced by a C-5 propynylcytosine, an oligonucleotide derivative in which the cytosine is replaced by a phenoxazine-modified cytosine, an oligonucleotide derivative in which the ribose is replaced by a 2'-O-propylribose, and an oligonucleotide derivative in which the ribose is replaced by a 2'-methoxyethoxyribose.

28. A DNA that has a nucleotide sequence represented by SEQ ID NO: 20 or 21.

29. A method for determining the expression level of a gene encoding the polypeptide of any one of claims 1 to 4, which comprises polymerase chain reaction using the oligonucleotide of any one of claims 26 to 28.

30. A method for detecting cancers and cancer metastasis, which comprises using the method of claim 25 or 29.

31. A method for inhibiting transcription of DNA coding for the polypeptide of any one of claims 1 to 4 or translation of its corresponding mRNA, which comprises using a DNA selected from DNAs of claims 5 and 26 to 28 and DNAs having a nucleotide sequence represented by SEQ ID NO: 2 or 3.

32. An antibody recognizing the polypeptide of any one of claims 1 to 4.

33. A method for immunological detection of the polypeptide of any one of claims 1 to 4, which comprises using the antibody of claim 32.

34. An immunohistostaining method, which comprises detecting the polypeptide of any one of claims 1 to 4 by using the antibody of claim 32.

35. An immunohistostaining agent comprising the antibody of claim 32.

36. A diagnostic reagent for cancers or cancer metastasis, which comprises the antibody of claim 32.

37. A method for screening a compound varying the activity of the polypeptide of any one of claims 1 to 4, which comprises contacting said polypeptide with a test sample.

38. A method for screening a compound varying the

expression of a gene coding for the polypeptide of any one of claims 1 to 4, which comprises contacting cells expressing said polypeptide with a test sample and determining the content of sialyl-Lewis a sugar chain, Lewis a sugar chain, Lewis b sugar chain or sialyl-Lewis c sugar chain by use of anti-sialyl-Lewis a antibody, anti-Lewis a antibody, anti-Lewis b antibody or anti-sialyl-Lewis c antibody.

39. A method for screening a compound varying the expression of a gene coding for the polypeptide of any one of claims 1 to 4, which comprises contacting cells expressing said polypeptide with a test sample and determining the content of said polypeptide by use of the antibody of claim 32.

40. A promoter DNA governing transcription of a gene coding for the polypeptide described in any one of claims 1 to 4.

41. A promoter DNA according to claim 40, which works in cells selected from the group consisting of small intestine cells, large intestine cells, pancreas cells, stomach cells, colon cancer cells, pancreatic cancer cells and stomach cancer cells.

42. A promoter DNA according to claim 40 or 41, which is a human- or mouse-derived promoter DNA.

43. A promoter DNA according to any one of claims 40 to 42, which comprises a 50- to 5000-bp consecutive nucleotide DNA sequence in the nucleotide sequence of 1 to 5000 in the nucleotide sequence represented by SEQ ID NO: 3.

44. A method for screening a compound varying the efficiency of transcription by the promoter DNA of any one of claims 40 to 43, which comprises transforming animal cells with a plasmid containing said promoter DNA and a reporter gene ligated downstream of said promoter DNA, then contacting the transformant with a test sample, and determining the content of a translation product of said reporter gene.

45. A screening method according to claim 44 wherein the reporter gene is a gene selected from the group consisting of a chloramphenicol acetyltransferase gene, a β-glucuronidase

gene, a β-galactosidase gene, a β-lactamase gene, a luciferase gene, an aequorin gene and a green fluorescent protein gene.

46. A knockout non-human animal wherein a DNA coding for the polypeptide of any one of claims 1 to 4 is rendered defective or mutated.

47. A knockout non-human animal according to claim 46 wherein the knockout non-human animal is a mouse.